DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2015

Summit Medical, Inc.
Nicole Dove
QA/RA Manager
815 Northwest Pkwy, Ste. 100
St. Paul, MN 55121

Re: K142630
Trade/Device Name: Instru-Safe® Instrument Protection System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Tray
Regulatory Class: II
Product Code: KCT
Dated: November 19, 2014
Received: November 26, 2014

Dear Ms. Nicole Dove:

This letter corrects our substantially equivalent letter of December 23, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number: K142630

Device Name: Instru-Safe® Instrument Protection System

Indications for Use:

Instru-Safe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed Genesis rigid containers. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in table 1.

Lumen claims for Four (4) Minute Pre-Vacuum Steam Sterilization Cycle:

Summit Cassette Model	Minimum Inside Diameter	Maximum Length	Number of Lumens
IN-2681	3mm	200mm	1
IN-2681	1mm	65mm	1
IN-0000	1mm	400mm	5
IN-0000	3mm	400mm	1
IN-0000	5mm	400mm	1
IN-6105	5mm	241mm	1

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter ____X_____
(Per 21 CFR 801.109)

Indications for Use Statement

The worst case validated load by vent-to-volume calculation is the IN-2681 tray.

The total weight of the container system (e.g. container, tray and instrument load) must not exceed 25 lbs.

Summit Medical, Inc. | 815 Northwest Parkway, Suite 100 | St. Paul, MN 55121 USA
phone: 651.789.3939 | **fax:** 651.789.3979
www.summitmedicalusa.com

Indications for Use Statement

Attachment 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-1315	30	3.5
IN-2681	13	0.64
IN-2682	13	0.89
IN-2683	13	1.39
IN-2840	36	8.75
IN-2842	24	6.5
IN-2843	36	8.75
IN-2880	56	12.1
IN-2900	22	4.18
IN-2950	12	4.1
IN-3030	34	9.5
IN-4000	20	3.2
IN-4003	30	3.25
IN-4010	10	1.98
IN-5401	6	2
IN-5401-02	2	1
IN-5401-03	2	1
IN-5401-08	8	3.2
IN-5401-12	12	3.25
IN-6103	2	2.15
IN-6105	2	2.15
IN-6110	3	2.15
IN-6203	2	2.75
IN-6205	2	2.75
IN-6210	2	2.75
IN-6240	2	2.75
IN-6303	2	3.28
IN-6305	2	3.28
IN-6310	2	3.28
IN-6403	2	3.28
IN-6405	2	3.28
IN-6410	2	3.28
IN-7010	2	2
IN-7012	1	1.07
IN-7032	2	1.1

IN-7120	45	11.25
IN-7130	45	13.5
IN-7150	8	1.9
IN-7153	6	1.7
IN-7223	10	9.2
IN-7274	30	8
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5
IN-7823	45	14.5
IN-7840	45	13.5
IN-7940	20	13.25
IN-8240	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8615	2	5.8
IN-8616	2	5.8
IN-8620	3	7.2
IN-8621	4	7.18
IN-8622	4	7.18
IN-8630	3	6.5
IN-8632	3	6.45
IN-8633	3	6.8
IN-8640	4	5.35
IN-8642	4	5.35
IN-8643	5	5.35
IN-8645	4	5.35
IN-8650	4	5.85
IN-8660	4	5.35
IN-8662	4	5.35
IN-8663	4	5.35
IN-8810	20	13.5
IN-8820	15	8.75
IN-8823	45	14
IN-8830	15	8.75
IN-8833	45	14
IN-8840	20	13.75

IN-8850	15	8.75
IN-8853	45	14
IN-8860	15	8.75
IN-8862	30	10.5
IN-8863	45	14
IN-8880	2	3.28
IN-8882	16	12.1
IN-8883	2	3.28
IN-8884	4	5.35
IN-8885	1	2.25
IN-8886	6	12.1
IN-8889	6	12.1
IN-8891-S	1	2
IN-8891-SI-12-S	1	2
IN-8891-SI-85-S	1	2
IN-8892-01	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8897	8	6
IN-8898	10	10.25
IN-8899	7	6.5
IN-8901	1	2.25
IN-8902	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8931	1	2.4
IN-8932	9	9.5
IN-8933	3	3.75
IN-8936	6	11.5
IN-8937	16	14.5
IN-8938	8	12.5
IN-8939	10	11.6
IN-8940	5	5.18
IN-8942	11	10
IN-8943	1	2.7
IN-8944	6	4.7
IN-8945	2	5.18

IN-8946	9	6.1
IN-8980-01	20	9.5
IN-8982-01	17	9.5
IN-8983-01	16	9.5
IN-8984-01	15	9.5
IN-8986-S	2	6.5
IN-8987-S	2	6.5
IN-8988-S	2	6
IN-8989-S	2	6
IN-9999-160	6	12.1
IN-9999-162-S	2	5.8
IN-9999-168-S	2	5.8
IN-9999-172-S	2	5.8
IN-9999-178-S	2	5.8

510(k) Summary

Following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92

Submitter:	Summit Medical Inc. 815 Northwest Parkway, Suite 100 St. Paul, MN 55121 Tel: (651) 789-3939
ER Number:	3008719017
Contact Person:	Nicole Dove QA/RA Manager Tel: (651) 789-3921 ndove@summitmedicalusa.com
Date Prepared:	December 22, 2014
Subject Device:	Trade Name(s): Instru-Safe® Instrument Protection System Classification Name: Sterilization wrap containers, trays, cassettes & other accessory (21 CFR 880.6850) Common Name: Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System Device Class: Class II Device Code: KCT Panel: General Hospital
Predicate Device:	Tradename: Instru-Safe Instrument Protection System 510(k) Holder: Summit Medical Inc. 510(k) #: K133015
Device Description:	Summit Medical Inc. Instru-Safe Instrument Protection System are cassettes / trays used to enclose and hold surgical instruments and accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes / trays by themselves do not maintain sterility.

<table>
<tr><td></td><td>The cassettes / trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes / trays have perforations to allow sterilant penetration. The cassettes / trays contain silicone inserts in the base and/or cover to hold, organize and protect the surgical instruments within the cassette / tray.</td></tr>
<tr><td rowspan="2">Intended Use:</td><td>Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed Genesis rigid containers. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.
Sterilization methods and configurations
• Autoclave Sterilization Parameter:
Cycle: Pre-Vacuum
Temperature: 270˚F (132˚C)
Minimum Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes
<table>
<tr><th>Summit Cassette Model</th><th>Minimum Inside Diameter</th><th>Maximum Length</th><th>Number of Lumens</th></tr>
<tr><td>IN-2681</td><td>3mm</td><td>200mm</td><td>1</td></tr>
<tr><td>IN-2681</td><td>1mm</td><td>65mm</td><td>1</td></tr>
<tr><td>IN-0000</td><td>1mm</td><td>400mm</td><td>5</td></tr>
<tr><td>IN-0000</td><td>3mm</td><td>400mm</td><td>1</td></tr>
<tr><td>IN-0000</td><td>5mm</td><td>400mm</td><td>1</td></tr>
<tr><td>IN-6105</td><td>5mm</td><td>241mm</td><td>1</td></tr>
</table></td></tr>
<tr><td>The intended use of the subject device includes the use of Genesis rigid containers and the intended use of the predicate device includes the use of Aesculap rigid containers. The difference in rigid containers is not critical and does not affect safety and effectiveness of the Instru-Safe Instrument Protection System.</td></tr>
<tr><td>Comparison of Characteristics to Predicate Device:</td><td>Based on a comparison of the design, technology, materials, manufacturing, performance, specifications and methods of use, the Instru-Safe Instrument Protection System is identical to the identified 510(k) cleared predicate device.</td></tr>
<tr><td>Performance Data:</td><td>Sterilization validation testing was performed to demonstrate Instru-Safe Instrument Protection System compatibility when used in a Four (4) minute pre-vacuum steam sterilization cycle within a Genesis rigid container.
Sterilization methods and configurations
• Autoclave Sterilization Parameter:
Cycle: Pre-Vacuum</td></tr>
</table>

	Temperature: 270˚F (132˚C) Minimum Exposure Time: 4 minutes Minimum Dry Time: 30 minutes
Conclusion:	Based upon intended use, performance data and technical information provided in this pre-market notification, the Instru-Safe Instrument Protection System described herein are substantially equivalent to current legally marketed predicate devices.

Substantial Equivalence – Device Comparisons

<table>
<tr><th>Characteristic Indications</th><th>New Device</th><th>Predicate Device Instru-Safe Instrument Protection Systems K133015</th></tr>
<tr><td>Indication for Use</td><td>Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed Genesis rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.

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<tr><td>IN-6105</td><td>5mm</td><td>241mm</td><td>4</td></tr>
</table></td><td>Instru-Safe Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe System cassettes are intended to be used in conjunction with central legally marketed wrap or Aesculap rigid container. The Instru-Safe System cassettes are not intended on their own to maintain sterility.

Sterilization methods and configurations
• Autoclave Sterilization Parameter:
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes
<table>
<tr><th>Summit Cassette Model</th><th>Aesculap Container Model</th></tr>
<tr><td>IN-8823-AE</td><td>*JN444</td></tr>
<tr><td>IN-2880</td><td>*JK444</td></tr>
<tr><td>IN-6105</td><td>*JN742</td></tr>
</table>
*Validated by Summit Medical for use in steam pre-vacuum sterilizers ONLY operating at 270˚F (132˚C) for 4 minutes</td></tr>
</table>

<table>
<tr><td></td><td>Validated by Summit Medical for use in steam pre-vacuum sterilizers ONLY operating at 270˚F (132˚C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.</td><td>exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.</td></tr>
<tr><th>Element</th><th>New Device</th><th>Predicate (K133015)</th></tr>
<tr><td>Intended Use</td><td>Instru-Safe ® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed Genesis rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.

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Sterilization methods and configurations
Autoclave Sterilization Parameter:
Cycle: Pre-vacuum
Temperature: : 270°F (132°C)
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*Validated by Summit Medical for use in steam prevacuum sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.</td></tr>
</table>

Material Composition	No changes from predicate device	The cassette contains components made of anodized aluminum, stainless steel, blue silicone, black silicone, polyester, ultem™ 1000
Physical Properties	Instru-Safe Instrument Protection System cassettes include - perforated base - perforated cover - silicone inserts (hold-it / hold down) - Handles - Latches - Feet - Posts (optional) - Divider (optional) - Shelf (optional)	Instru-Safe Instrument Protection System cassettes include - perforated base - perforated cover - silicone inserts (hold-it / hold down) - Handles - Latches - Feet - Posts (optional) - Divider (optional) - Shelf (optional)
Configurations/ Dimensions	Various configurations / dimensions, refer to section 14a	See table located in predicate device submission K133015
Performance	New Device	Predicate (K133015)
Sterilant Penetration	Pre-Vacuum Steam No Change	Pre-Vacuum Steam 270°F (132°C), 4 minutes
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	No change	Refer to predicate device K133015
Shelf Life	No change	Reusable (5 year accelerated shelf life study)
Drying Time	No change	Autoclave Sterilization Parameter: 4 minute 270˚C (132°C) Minimum Dry Time: - 30 minute
Technological Characteristics:	The technological characteristics of the subject devices are equivalent to the predicate devices. The cassettes / trays are made of standard medical grade materials and do not incorporate any new technological characteristics.	
Performance Data:	Sterilization validation testing was performed to demonstrate Instru-Safe Instrument Protection System compatibility when used in a Four (4) minute pre-vacuum steam sterilization cycle within a Genesis rigid container.	

	Sterilization methods and configurations • Autoclave Sterilization Parameter Cycle: Pre-Vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes